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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAM 2 0009	3665

7590 09/23/2005

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,340	SHODAI ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8 and 10-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 10-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 07/11/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7, 10-17, and 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl US 4,724,136 or Dugger, III US 5,955,098, in view of Borkan et al. US 4,935,243.

Scheibl discloses a confectionery preparation in the form of chewable capsules, tablets, chewing gums, wafer and the like comprising a fill material (see abstract; and column 1, lines 30-55). The fill material comprises cacao powder, flavoring and coloring agents (example 1). The filled further comprises drugs or active agents disclosed in column 2, lines 51-65.

Dugger discloses a soft bite gelatin capsule comprising a paste fill composition contains flavoring agent, sweetening agent, active compound, and excipient (see abstract, column 3, lines 12-62). Example 12 discloses a capsule fill comprising chocolate powder in an amount of about 46.67%, and nicotine (active agent) in an amount of 0.185%.

Scheibl or Dugger, III is relied upon for the reason stated above. The references do not explicitly teach the capsule shell as claimed in claim 19. However Dugger incorporates Borkan by reference for the teaching of chewable soft gelatin capsule.

Borkan teaches a chewable, edible soft gelatin capsule comprising a solid or semi-solid fill material (see abstract; and column 3, lines 1-5). The gelatin shell comprises gelatin, glycerin as a plasticizer, D-sorbitol, and sweetener (columns 3-4; and column 5, lines 1-36). Thus, it would have been obvious for one of ordinary skill in the art to use the chewable, edible soft gelatin capsule of Borkan to encapsulate the fill material of Scheibl or Dugger, because the references teach the use of soft gelatin capsule suitable for chewing.

Claims 1, 2, 4-7, 10-17 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Ebert et al. US 4532126.

Scheibl or Dugger, III is relied upon for the reason stated above. Neither Scheibl nor Dugger explicitly teach the capsule shell as claimed in claim 19.

Ebert teaches a chewable soft gelatin capsule comprising gelatin, water, a plasticizer and a masticatory substance (Col. 54-68). The plasticizer is glycerin or sorbitol (Col. 2, lines 54-60). The capsule is filled with candy confectionaries, antacids, cough preparations, cold preparations, sore throat remedies, antiseptics, dental preparations, dextromethorphan, and/or acetaminophen (Col. 3, line 67 - Col. 4, line 3; Col, 5; Example 11; Col. 6, Example IV). The capsules also contain taste modifiers or flavoring agents (Col. 4,lines 1 3-25). Thus, it would have been obvious for one of

ordinary skill in the art to use the chewable soft gelatin capsule of Ebert to encapsulate the fill material of Scheibl or Dugger, because the references teach the use of soft gelatin capsule suitable for chewing.

Claims 8 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dugger, III, in view of Ebert et al. US 4532126 and Oohashi et al. US 5,859,048.

Dugger in view of Ebert are relied upon for the reasons stated above. Dugger does not expressly teach the use of the filled material claimed in claim 8.

Oohashi teaches a pharmaceutical composition for oral mucosal administration containing additives including cacao butter, coconut oil, lard, and macrogol (column 3, lines 23-45). Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Dugger using the additives in view of the teaching of Oohashi, because Oohashi teaches a composition that improved mucosal absorbability (column 5, lines 8-12), and because Dugger teaches a composition that provides rapid absorption through the oral mucosa (abstract).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scheibl or Dugger, III, in view of Mehta US 5,084,278.

Neither Scheibl nor Dugger does teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9,

lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to use chocolate flavor as the flavoring agent for the fill material taught by Scheibl or Dugger, because the references teach the use of flavoring agent suitable for taste masking of active agents acceptable for chewing composition.

Response to Arguments

Applicant's arguments filed 07/11/05 have been fully considered but they are not persuasive. The 103(a) rejections are maintained, and the 102 rejections have been withdrawn, nonetheless.

Applicant discloses that claim 8 was not rejected as anticipated or obvious over any of the cited references. In response to applicant's remark, amended claim 8 filed on 10/22/04 was rejected under 112, 2nd paragraph because the language was confusing, and it might read as combination of lard, coconut oil, and macrogol. Therefore, the claim was not rejected under prior art. The claim is now amended to read in an alternative manner, therefore, it is now included in the obviousness rejections.

Applicant argues that neither Scheibl nor Dugger teach that the fill material in their capsules is subjected to aging. Therefore, the two references do not anticipate the amended claims. In response to applicant's argument, it is noted that the rejected claims are drawn to composition claims, except for claims 29 and 30. Determination of patentability is based on the product itself even though product-by-process claims are limited by and defined by the process. The patentability of a product does not depend

on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The cited references teach soft capsule containing the claimed fill material, namely, fill material in a solid or semi-solid form.

Regarding the 103(a) rejection over Scheibl or Dugger in view of Borkan or Ebert, applicant argues that neither Borkan nor Ebert remedy the deficiencies of Scheibl and Dugger regarding aging the fill material. Scheibl or Dugger in view of Borkan is maintained in view of the above reason. For claims 29 and 30, Ebert teaches drying the freshly made capsule until for a suitable length of time until the desired chewing characteristics are attained (see abstract; column 2, lines 46-54; column 4, lines 37-41; and examples). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation modify the teaching of either Scheibl or Dugger to dry the final capsule in the suitable length of time in order to obtain a capsule containing solid or semi-solid useful in pharmaceutical art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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